# **EXHIBIT E**

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the matters of

Walgreen Co.

Docket Nos. 13-1, 13-9, 13-10, 13-11 (Consolidated)

ADMINISTRATIVE LAW JUDGE JOHN J. MULROONEY, II

# $\frac{\textbf{RESPONDENTS' CONSOLIDATED PREHEARING STATEMENT IN THE}}{\underline{\textbf{PHARMACY MATTERS}}}$

Pursuant to the Court's December 31, 2012 Order for Prehearing Statements and January 10, 2013 Ruling On Respondents' Motion To Consolidate, Walgreen Co. ("Walgreens," "Respondent," or "the Company"), hereby submits its Consolidated Prehearing Statement for dockets 13-9, 13-10, and 13-11 (the "Pharmacy Matters"). Walgreens previously submitted a Prehearing Statement and Supplemental Statement for docket 13-1 regarding Walgreens' Jupiter Distribution Center (the "Jupiter Facility Matter").

#### I. ISSUE

Whether the Drug Enforcement Administration ("DEA") can prove that it would be inconsistent with the public interest for each of the following three Walgreens pharmacies to retain their registrations pursuant to 21 U.S.C. § 824(a)(4): (1) Walgreen pharmacy #06997 in Oviedo, FL, registration BW8487438 ("Walgreens #06997"); (2) Walgreens pharmacy #04727 in Ft. Pierce, FL, registration BW6561270 ("Walgreens #04727"); and (3) Walgreen pharmacy #03629 in Hudson, FL, registration BW4713992 ("Walgreens #03629") (collectively, the "Pharmacies").

#### II. REQUESTED RELIEF

Walgreens requests that this Court recommend denial of DEA's request that the Pharmacies' registrations be revoked.

#### III. PROPOSED STIPULATIONS OF FACT

#### A. Quotations of Prior DEA Statements

1. When evaluating the validity of a prescription for a controlled substances, rather than focusing on any particular factor, it is critical to bear in mind that (i) the entirety of circumstances must be considered, (ii) the cases in which physicians have been found to have prescribed controlled substances improperly typically involve facts that demonstrate blatant

criminal conduct, and (iii) the percentage of physicians who prescribe controlled substances improperly (or are investigated for doing so) is extremely small.<sup>1</sup>

- 2. There is a lack of consensus among physicians as to all the circumstances that warrant the use of opioids to treat pain.<sup>2</sup>
- 3. What constitutes an inordinately large quantity of controlled substances ... can vary greatly from patient to patient.<sup>3</sup>
- 4. DEA does not apply a greater level of scrutiny to the prescribing of controlled substances to treat pain as compared to other ailments. Regardless of the ailment, DEA applies evenhandedly the requirement that a controlled substance be prescribed for a legitimate medical purpose in the usual course of professional practice. The idea that prescribing opioids to treat pain will trigger special scrutiny by DEA is false.<sup>4</sup>
- 5. One cannot provide an exhaustive and foolproof list of "dos and don'ts" when it comes to prescribing controlled substances for pain or any other medical purpose.<sup>5</sup>
- 6. There are no definitive criteria laying out precisely what is legally permissible, as each patient's medical situation is unique and must be evaluated based on the entirety of the circumstances.<sup>6</sup>

<sup>&</sup>lt;sup>1</sup> Dispensing Controlled Substances for Treatment of Pain, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006) (verbatim DEA quote).

<sup>&</sup>lt;sup>2</sup> *Id.* at 52718 (verbatim DEA quote).

<sup>&</sup>lt;sup>3</sup> Id. at 52720 (verbatim DEA quote).

<sup>&</sup>lt;sup>4</sup> *Id.* (verbatim DEA quote).

<sup>&</sup>lt;sup>5</sup> Id. at 52719 (verbatim DEA quote).

<sup>&</sup>lt;sup>6</sup> Id. (verbatim DEA quote).

7. The types of cases in which physicians have been found to have dispensed controlled substances improperly under Federal law generally involve facts where the physician's conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.<sup>7</sup>

- 8. It is not possible to expand on the phrase "legitimate medical purpose in the usual course of professional practice," in a way that will provide definitive guidelines that address all the varied situations physicians might encounter.<sup>8</sup>
- 9. DEA presumes ... that most physicians provide appropriate amounts of pain medication.
- 10. It is not DEA's role to issue medical guidelines specifying patient characteristics that warrant the selection of a particular opioid or other medication or regimen for the treatment of pain.<sup>10</sup>
- DEA does not regulate the general practice of medicine. The responsibility for educating and training physicians so that they make sound medical decisions in treating pain (or any other ailment) lies primarily with medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise.<sup>11</sup>
- 12. DEA ... has neither the legal authority nor the expertise to provide medical training to physicians or issue guidelines that constitute advice on the general practice of

<sup>&</sup>lt;sup>7</sup> Id. at 52717 (verbatim DEA quote).

<sup>&</sup>lt;sup>8</sup> *Id.* (verbatim DEA quote).

<sup>&</sup>lt;sup>9</sup> *Id.* at 52718 (verbatim DEA quote).

<sup>&</sup>lt;sup>10</sup> *Id.* (verbatim DEA quote).

<sup>11</sup> Id. at 52719 (verbatim DEA quote).

medicine.12

- 13. The amount of dosage units per prescription will never be a basis for investigation of the overwhelming majority of physicians.<sup>13</sup>
- 14. Some physicians who treat patients having a history of drug abuse require each patient to a contract agreeing to certain terms designed to prevent diversion and abuse, such as periodic urinalysis. While such measures are not mandated by the CSA and DEA regulations, they can be very useful.<sup>14</sup>
- 15. DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes. In fact, the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by Federal or State law enforcement officials.<sup>15</sup>
- and II controlled substances in order to avoid the overproduction of these substances, for the purposes of reducing the risk of diversion to illicit traffic. Accordingly, the quota system serves the vital purpose of reducing the risk of diversion.<sup>16</sup> DEA's aggregate production quota for oxycodone (for sale) has more than doubled over the last seven years, from 56,000,000 grams in 2006, to a currently established production quota of 131,500,000 grams for 2013.<sup>17</sup>

<sup>&</sup>lt;sup>12</sup> *Id.* (verbatim DEA quote).

<sup>&</sup>lt;sup>13</sup> Id. at 52723 (verbatim DEA quote).

<sup>&</sup>lt;sup>14</sup> *Id.* (verbatim DEA quote).

<sup>&</sup>lt;sup>15</sup> Id. at 52719 (verbatim DEA quote).

Warning: The Growing Danger of Prescription Drug Diversion: Hearing Before the Subomm. on Commerce, Manufacturing, and Trade of the H. Comm. on Energy & Commerce, 111th Cong. 3-4 (2011) (statement of Michele M. Leonhart, Administrator, Drug Enforcement Administration) (verbatim quote).

<sup>&</sup>lt;sup>17</sup> See DEA Notice, Controlled Substances: Final Revised Aggregate Production Quotas for 2006, 71 Fed. Reg. 61803 (Oct. 19, 2006); DEA Notice, Controlled Substances: Final Revised Aggregate Production Quotas for 2007, 72 Fed. Reg. 48686 (Aug. 24, 2007); DEA Notice,

- 17. Until 2010, Fla. Stat. § 465.0276 allowed a practitioner to dispense drugs in the usual course of professional practice so long as s/he was registered as such and paid a \$100 fee. In 2010, the Florida legislature amended Fla. Stat. § 476.0276 to prohibit a registered practitioner from dispensing more than a 72-hour supply of any controlled substance for any patient who paid for the medication with cash, check or credit card. The law became effective October 1, 2010. Finally, in 2011, the Florida legislature amended the statute a second time to prohibit a practitioner, except in very limited circumstances, from dispensing any controlled substances in Schedules II and III. The law became effective July 1, 2011. <sup>18</sup>
- 18. In October 2010, Florida passed legislation severely restricting the ability of pain clinics to dispense controlled substances. The purpose of this legislation was to combat the severe abuse of prescription drugs dispensed directly from [pain] clinics. After the law was enacted, pharmacies in Florida experienced a substantial increase in requests to dispense controlled substances.<sup>19</sup>
- 19. Just as illicit drug traffickers and organizations adapt to law enforcement methods, pharmaceutical traffickers adapt to and circumvent laws that attempt to stop the flow of

Controlled Substances: Final Revised Aggregate Production Quotas for 2008, 73 Fed. Reg. 66939 (Nov. 12, 2008); DEA Notice, Controlled Substances: Final Revised Aggregate Production Quotas for 2009, 74 Fed. Reg. 54077 (Oct. 21, 2009); DEA Notice, Controlled Substances: Final Revised Aggregate Production Quotas for 2010, 75 Fed. Reg. 55828 (Sept. 14, 2010); DEA Notice, Controlled Substances: Final Adjusted Aggregate Production Quotas for 2011, 76 Fed. Reg. 77016 (Dec. 9, 2011); DEA Notice, Controlled Substances: Final Adjusted Aggregate Production Quotas for 2012, 77 Fed. Reg. 55500 (Sept. 10, 2012); DEA Notice, Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2013, 77 Fed. Reg. 59980 (Oct. 1, 2012).

Declaration of DEA Counsel Scott Lawson, *In Re: Administrative Subpoena*, 1:12-mc-43 (E.D. Va.), Dkt. No. 34-2, ¶ 21.

<sup>&</sup>lt;sup>19</sup> Id. at ¶10 (verbatim quote).

controlled substance pharmaceuticals into the illicit market.<sup>20</sup>

**20.** In mid to late 2011 and continuing into 2012, Walgreens undertook to reduce the volume of oxycodone dispensing at its high-volume pharmacies and in some cases, did, in fact, achieve a relatively significant reduction in Schedule II dispensing at these stores.<sup>21</sup>

# B. Proposed Stipulations Regarding 2011 Memorandum of Agreement

- 21. In April 2011, DEA and Walgreens entered into a Memorandum of Agreement ("2011 MOA"). The 2011 MOA became effective on April 7, 2011.
  - 22. Respondents' Exhibit 289 is an authentic copy of the 2011 MOA.
- 23. The 2011 MOA is applicable "to all current and future Walgreens walk-in, retail pharmacy locations registered with the DEA to dispense controlled substances."<sup>22</sup>
- 24. In the 2011 MOA, DEA "release[d] and agree[d] to refrain from filing any administrative actions against Walgreens' DEA registrations based on the Covered Conduct or similar conduct at any other Walgreens pharmacy on or before the effective date of this agreement, within DEA's enforcement authority under 21 U.S.C. §§ 823 and 824."<sup>23</sup>
- 25. Among the conduct described in the 2011 MOA as "Covered Conduct" are allegations regarding: (1) dispensing controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed; (2) dispensing controlled substances based on prescriptions issued by physicians for other than a legitimate medical purpose; (3) dispensing controlled substances to individuals that Walgreens knew or should have known were diverting controlled substances; (4) refilling prescriptions for controlled substances too early;

<sup>&</sup>lt;sup>20</sup> Responding to the Prescription Drug Abuse Epidemic: Hearing Before the S. Caucus on Int'l Narcotics Control, 112th Cong. (2012) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Administration) (verbatim quote)

Order to Show Cause and Immediate Suspension of Registration, Jupiter Matter, Sept. 13, 2012,¶ 20 (verbatim DEA quote).

<sup>&</sup>lt;sup>22</sup> 2011 MOA, Part I.

<sup>&</sup>lt;sup>23</sup> 2011 MOA § 5.

and (5) filling prescriptions that were issued using expired DEA registrations number.<sup>24</sup>

- 26. The conduct described by DEA in its OSCs and Prehearing Statements in the Pharmacy Matters is the basis on which DEA seeks to revoke the Pharmacies' registrations.
- 27. The following allegations in DEA's Prehearing Statement for Walgreens #04727 involve conduct that pre-dates April 7, 2011:
  - a. "[B]etween January 1, 2010 and March 21, 2012, Respondent filled 723 controlled substance prescriptions issued by Dr. Kenneth Pearlberg, an ophthalmologist, located approximately 69 miles from Respondent in Boca Raton." Gov.'s Walgreens #04727 PHS at 11 (proposed testimony of Gayle Lane; footnote omitted).
  - b. "[B]etween January 1, 2010 and April 2012, Respondent dispensed at least 657 controlled substance prescriptions issued by Dr. Alexandra Taylor, certified in obstetrics and gynecology, located in Del Ray Beach, Florida." *Id.* (proposed testimony of Gayle Lane; footnote omitted).
  - c. "[B]etween January 1, 2010 and April 2012, Respondent dispensed at least 745 controlled substance prescriptions issued by Dr. Ralph Miniet, a pediatrics specialist, located approximately 90 miles from Respondent in Fort Lauderdale, of which 73% of the prescriptions were for oxycodone and alprazolam cocktails." *Id.* (proposed testimony of Gayle Lane; footnote omitted).
  - d. "20 prescriptions for oxycodone dispensed by Respondent between March 2011 and December of 2011 despite its own pharmacists' warnings or noted 'red flags' concerning the physicians." *Id.* at 12 (proposed testimony of Gayle Lane; footnote omitted).
  - e. Conduct at Walgreens #04727 occurring "for a period of about six months in 2010/2011." *Id.* at 14; *id.* at 18-19 (proposed testimony of George Corripio).
  - f. Walgreens' Orlando central fill facility and prescriptions from "between January 2010 and April 2012." *Id.* at 15-16 (proposed testimony of Linda Stocum); see also id. at 17-18 (proposed testimony of Dianne Williams).

<sup>&</sup>lt;sup>24</sup> 2011 MOA Part II and Part III(3).

- g. Guidance Andrea Cohen "received with respect to the growth of oxycodone customers in 2010 and 2011 and dispensing guidance from her supervisor" and "guidance she provided to other pharmacy staff on how to resolve red flags pertaining to controlled substance prescriptions." *Id.* at 20 (proposed testimony of Andrea Cohen).
- h. "[O]xycodone customer traffic at Respondent's location between 2010 through 2011" and an email to Wesley Rohn dated January 5, 2011. *Id.* at 20-21 (proposed testimony of Joseph Berdie).
- i. Alleged conduct by Mr. Rohn occurring in "December 2010" and on "November 23, 2010." *Id.* at 21. (proposed testimony of Wesley Rohn).
- j. Concerns that Edward Svihra, "Doug Lemmons and Ken Amos discussed in January 2011 regarding Respondent's oxycodone dispensing" and a "pharmacist's hotline complaint received in 2011" *Id.* at 21-22 (proposed testimony of Edward Svihra).
- k. Mr. Lemmons's "concerns identified in January 2011 and discussed with Mr. Svihra and Ken Amos regarding Respondent's oxycodone dispensing." *Id.* at 22 (proposed testimony of Doug Lemmons).
- 1. Professor Doering's "analysis of Respondent's controlled substance dispensing between January 1, 2010 and April 4, 2012." *Id.* at 26. (proposed testimony of Paul Doering).
- m. A chart "illustrat[ing] the increase in Respondent's average daily dispensing of controlled substances. In the first six months of 2010, Respondent dispensed on average 35.3 controlled substance prescriptions per day. In the first six months of 2011, that number rose to an average of 72.5 prescriptions dispensed per day." *Id.* at 26 (proposed testimony of Paul Doering).
- 28. The following allegations in DEA's Prehearing Statement for Walgreens #06997 involve conduct that pre-dates April 7, 2011:
  - a. "Walgreens #06997 significantly increased its oxycodone purchases between 2009 and 2011." Gov.'s Walgreens #06997 PHS at 4 (proposed testimony of Susan Langston).
  - b. "Walgreens representatives were told that the average US pharmacy purchased 69,500 dosage units of oxycodone in 2010, whereas the average Florida pharmacy purchased 134,000 dosage units of oxycodone in 2010. DPM Langston will testify that the summary chart entitled '2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone' was discussed at the meeting and provided to Walgreens official Dwayne Piñon." *Id.* at 6 (proposed testimony of Susan Langston).

- c. "[T]wo hundred sixty eight (268) prescriptions for controlled substances filled for Dr. Anthony Wicks under registration BW7987184 between December 2010 and July 2011." *Id.* at 7 (proposed testimony of Susan Slyker).
- d. Individuals allegedly arrested and supplied with controlled substances including "Sean Reynolds, arrested November 11, 2010 for illegal distribution of Xanax; Frederick J. Goepel, arrested January 12, 2011 for illegal distribution of oxycodone; Clinton Brekke, arrested January 20, 2011 for possession with intent to sell oxycodone; Valerie Brekke, involved in the arrest of Clinton Brekke for possession with intent to sell oxycodone; Matthew S. Miller and Timothy Kemp Dawson, arrested January 21, 2011 for illegal distribution of oxycodone; Brian Lee Kemm, arrested on January 26, 2011 for illegal distribution of oxycodone; and, Staci Lynn Starling and Anna Marie Girst, involved in the arrest of Kemm as the customers purchasing illegal controlled substances." *Id.* at 9 (proposed testimony of Deborah George).
- "Walgreens #06997 filled controlled substance prescriptions for some of e. the arrested customers subsequent to these arrests and notifications to Walgreens #06997. Clinton Brekke was arrested on January 20, 2011 and Chief Chudnow notified Walgreens in a letter dated January 21, 2011. Subsequently, Walgreens #06997 filled prescriptions for Mr. Brekke on March 13, April 7 and April 11, 2011. In the same letter regarding the arrest of Clinton Brekke, Valerie Brekke was identified as involved in the oxycodone-related arrest. Nonetheless, Walgreens #06997 filled prescriptions for Valerie Brekke for oxycodone on March 16 and April 25, 2011. In Chief Chudnow's January 27, 2011 letter, Staci Lynn Starling was noticed as a party purchasing oxycodone from Brian Lee Klemm. Nonetheless, Walgreen's #06997 dispensed alprazolam, hydromorphone and oxycodone to Ms. Starling on February 15, March 14 and April 13, 2011." *Id.* (proposed testimony of Deborah George).
- f. Walgreens' Orlando central fill facility and prescriptions from "between January 2010 and April 2012." *Id.* at 10 (proposed testimony of Linda Stocum).
- g. "The Oveido Police Department (OPD) made numerous arrests for illegal distribution of controlled substances in 2010 and 2011 related to controlled substances dispensed at the two Walgreens pharmacies, Walgreens #06997 and Walgreens #04251, with many of the illicit transactions preceding these arrests occurring in the parking lots of the stores." *Id.* at 12 (proposed testimony of Jeffrey Chudnow).

- h. "On February 10, 2011, Chief Chudnow met with Ed Lanzetti, Walgreens Market Loss Prevention Director, and another Walgreens official," statistics presented at that meeting, and subsequent filling of prescriptions. *Id.* at 12-13 (proposed testimony of Jeffrey Chudnow).
- i. "On March 15, 2011, Chief Chudnow sent letters to Alan G. McNally, Chairman of Walgreens Corporation and to Gregory D. Wasson, President and CEO of Walgreens Corporation." *Id.* at 13 (proposed testimony of Jeffrey Chudnow).
- j. Professor Doering's "analysis of Walgreens #06997's controlled substance dispensing between January 1, 2010 and April 4, 2012." *Id.* at 17 (proposed testimony of Paul Doering).
- 29. The following allegations in DEA's Prehearing Statement for Walgreens #03629 involve conduct that pre-dates April 7, 2011:
  - a. Analysis related to "an electronic dispensing log for all Schedule II-IV controlled substances dispensed by Walgreens #03629 between January 1, 2010 and April 4, 2012." Gov.'s #03629 PHS at 8 (proposed testimony of Gayle Lane).
  - b. "[O]n December 21, 2010, the PCSO received a call from Walgreens #03629 pharmacist Caren Cohalla (Ms. Cohalla) regarding an individual who attempted fill a fraudulent oxycodone prescription." *Id.* at 9 (proposed testimony of Janet Pascalli); *see also id.* at 14-15 (proposed testimony of Caren Cohalla).
  - c. Analysis related to "inventory records, copies of all Schedule II prescriptions, and dispensing records for Schedule II-IV controlled substances dispensed between January 1, 2010 and April 4, 2012." *Id.* at 11 (proposed testimony of Peter Flagg).
  - d. "From June 5, 2010 through August 11, 2010, Walgreens #03629 filled eight prescriptions for the aforementioned drug cocktail (oxycodone, alprazolam and Soma) issued by John T. Legowik, M.D. (Dr. Legowik) of Fort Myers, Florida." *Id*.
  - e. "From September 3, 2010 through February 5, 2011, Walgreens #03629 filled 40 prescriptions for the aforementioned drug cocktail issued by Paul J. Glusman, D.O. of Deerfield Beach, Florida." *Id*.
  - f. "From January 9, 2010 through November 7, 2011, Walgreens #03629 filled 1,550 controlled substance prescriptions issued by Robert R. Reppy, D.O. (Dr. Reppy) of Tampa, Florida." *Id*.

- g. Analysis related to Investigator Flagg's "review of Walgreens #03629's purchases of oxycodone from January 1, 2010 through April 4, 2012, and his comparison of the pharmacy's purchases of oxycodone with 14 pharmacies within the same zip code area (zip code 34667)." *Id.* at 12-13.
- h. Professor Doering's "analysis of Walgreens #03629's controlled substance dispensing between January 1, 2010 and April 4, 2012." *Id.* at 20 (proposed testimony of Paul Doering).

#### C. Other Proposed Stipulations

- 30. In May 2012, Walgreens voluntarily discontinued dispensing all Schedule II drugs as well as alprazolam and carisoprodol at the Pharmacies, and at five additional Florida pharmacies.
- 31. The Pharmacies did not utilize a central fill pharmacy in connection with dispensing Schedule II drugs.
- 32. In November 2012, prior to DEA issuing the OSCs, Walgreens informed DEA that it had voluntarily discontinued utilizing the Orlando central fill pharmacy in connection with dispensing controlled substances.
- 33. Florida became the epicenter of prescription drug diversion because—until recently—Florida had weak regulatory oversight of pain management practices, limited oversight of physician dispensing habits, and a non-operational statewide Prescription Drug Monitoring Program (PDMP).<sup>25</sup>

<sup>&</sup>lt;sup>25</sup> Pamela Jo Bondi, Florida Attorney General, "Florida's Roadmap to End its Prescription Drug Abuse Epidemic," Testimony to House Energy and Commerce Committee, Subcommittee on Commerce, Manufacturing & Trade (Mar. 1, 2012) (verbatim quote of Florida Attorney General's testimony before U.S. Congress).

#### IV. AGREED STIPULATIONS OF FACT

- Walgreens agrees with all stipulations of fact proposed by DEA in its Prehearing Statement regarding Walgreens #06997 ("Gov.'s Walgreens #06997 PHS").
- 2. Walgreens agrees with the following stipulations of fact proposed by DEA in its Prehearing Statement regarding Walgreens #04727 ("Gov.'s Walgreens #04727 PHS"): stipulation 1, 3, 4, and 6.
- 3. Walgreens agrees with the following stipulations of fact proposed by DEA in its Prehearing Statement regarding Walgreens #03629 ("Gov.'s Walgreens #04727 PHS"): stipulation 1, 9, 10, 11, and 12.

#### V. STATEMENT OF THE CASE

Walgreens #06997 is located in Oviedo, FL, Walgreens #04727 is located in Ft. Pierce, FL, and Walgreens #03629 is located in Hudson, FL. These pharmacies, like pharmacies across Florida, experienced increased demand for oxycodone and other prescriptions following Florida legislation that channeled demand for millions of oxycodone dosage units per month into the retail pharmacy market. This was a challenging time for Walgreens and other pharmacies statewide. But Walgreens pharmacists and district and market leaders recognized the challenges caused by the increased demand soon thereafter and began implementing additional controls to assist pharmacists with identifying problematic prescriptions and prevent patients and doctors from unlawfully diverting controlled substances. Walgreens did not turn a blind eye to the problem or wait for DEA to force it to act; it identified and addressed the issue many months before DEA intervened. And by the time DEA executed its Administrative Inspection Warrants at the Pharmacies, Walgreens' efforts had already substantially reduced the volume of oxycodone dispensed. Walgreens' actions demonstrate that it successfully worked to reduce levels of oxycodone dispensing and prevent diversion. Accordingly, revocation of these

pharmacy registrations is not in the public interest.

First, as the Attorney General of Florida stated before Congress, "Florida became the epicenter of prescription drug diversion because—until recently—[Florida] had weak regulatory oversight of pain management practices, limited oversight of physician dispensing habits, and a non-operational statewide Prescription Drug Monitoring Program (PDMP)." In October 2010, Florida passed legislation that restricted the ability of physicians to dispense directly to their patients. According to DEA's own data, this had the result of channeling the approximately 8 million dosage units of oxycodone previously dispensed by physicians into the retail pharmacy market—a market of which Walgreens has an approximate 30% market share. Not surprisingly, as DEA itself acknowledges, pharmacies across the state experienced "a substantial increase in requests to dispense controlled substances." These requests, in many cases, came from patients and doctors who previously had no relationship with Walgreens. As demand continued to increase, and as patterns developed and red flags emerged, the pharmacies implemented controls and limitations intended to prevent improperly dispensing prescriptions. Some of these controls worked quickly. Some took longer. As DEA has stated, "just as illicit drug traffickers and organizations adapt to law enforcement methods, pharmaceutical traffickers adapt to and circumvent laws that attempt to stop the flow of controlled substance pharmaceuticals into the illicit market." But Walgreens continued to implement controls and turn away questionable prescriptions—often in partnership with local law enforcement or local DEA agents who praised Walgreens for its commitment to ferretting out diversion—and today continues to work at improving and refining its systems for ensuring compliance with the law and ethical practice of pharmacy.

Second, Walgreens' efforts worked. Well before DEA executed warrants in the

Pharmacy Matters, Walgreens' controls had the effect of reducing the volume of oxycodone dispensed substantially. DEA agrees. The Order to Show Cause in the Jupiter Matter states: "In mid to late 2011 and continuing into 2012, Walgreens undertook to reduce the volume of oxycodone dispensing at its high-volume pharmacies and in some cases, did, in fact, achieve a relatively significant reduction in Schedule II dispensing at these stores."

Third, revocation is not in the public interest and is too broad a remedy in this matter. These were unprecedented circumstances. Walgreens recognizes that its efforts were not always perfect, and that its remedial actions at certain pharmacies required a longer period of time to achieve their full effects. But perfection is not the standard for revocation, and the public interest is served by pharmacies operated by companies that proactively respond to the challenges they face, as occurred here. Walgreens firmly believes that the public is better served by the continued registration of these pharmacies, with pharmacists, District Supervisors, Market Supervisors, and corporate leaders committed to fighting prescription drug abuse and diversion, in partnership with DEA.

#### VI. PROPOSED WITNESSES

Walgreens incorporates by reference the witness list contained in Respondents' Consolidated Witness and Exhibit List, filed concurrently with this Prehearing Statement per this Court's January 10, 2013 Ruling On Respondents' Motion To Consolidate. In addition, Walgreens reserves the right to call any witnesses listed by DEA on the matters identified by DEA.

### VII. SUMMARY OF TESTIMONY<sup>26</sup>

#### A. Witnesses Whose Testimony Is Applicable To Multiple Pharmacies

# 1. Rex Swords, Divisional Vice President, Centralized Pharmacy and Operations Support Services

Rex Swords will describe the Walgreens corporate structure and the responsibilities of the Company's different departments, the steps the Company took in response to pain clinic issues in Florida (including describing the anti-diversion controls that were already in place and the controls that were developed in response to the new challenges the Company faced), how those steps (prior to DEA's administrative warrants) had the effect of drastically reducing the volume of oxycodone dispensed from the Pharmacies and the Company's other Florida pharmacies, and how the Company improved its systems to ensure that, today, the Company is able to quickly identify problems at its pharmacies.

Specifically, Mr. Swords will describe his role as Divisional Vice President, Centralized Pharmacy and Operations Support Services, and his background, education, and training. He will describe the scope and organization of Walgreens' operations across the United States and Florida specifically. Mr. Swords will describe his responsibility within the Company to lead a team to assess and improve Walgreens' controlled substances compliance, with a specific focus on ensuring that Walgreens' vertically integrated business units work effectively toward this end. He will explain that Walgreens has multiple overlapping business structures and policies that should, among other things, serve as cross-checks to ensure proper training, handling and oversight regarding controlled substances within the Company, including at its pharmacies.

Walgreens has identified witnesses it may call to ensure compliance with this Court's December 31, 2012 Order. In addition to the testimony set forth herein, such witnesses will be prepared to address specific testimony from DEA's case in chief. To the extent the testimony described herein is cumulative or otherwise unnecessary to address DEA's actual case, Walgreens will reduce the number of witnesses and the scope of their testimony at trial.

Mr. Swords will testify that following changes in Florida law that occurred in 2010 and 2011, many retail pharmacies across the state, including the Pharmacies, saw an increase in the number of prescriptions presented for oxycodone and other drugs. He will testify that Walgreens pharmacists were expected to use their professional judgment when deciding whether to fill these prescriptions.

Mr. Swords will testify that Walgreens anticipated that the 2010 change in Florida's pain clinic law would increase the number of legitimate prescriptions for oxycodone prescriptions at Walgreens pharmacies, but that Walgreens could not predict how much those numbers would increase, or at what volume diversion was likely.

Mr. Swords will testify that even at the height of the dispensing volume associated with the Pharmacies, the pharmacists at those stores were simultaneously refusing to fill a substantial number of prescriptions. Mr. Swords will testify that in 2010-2011—long before the first DEA administrative subpoenas were served—Walgreens more fully appreciated the unique problems Florida's legislative policies caused and it began to take aggressive steps to ensure that prescriptions for oxycodone were being dispensed appropriately. Walgreens personnel worked diligently to address these issues, but found them very difficult to resolve quickly. Mr. Swords will testify that by mid-2011, through a combination of these proactive steps, the level of oxycodone being dispensed from the Pharmacies decreased substantially. Mr. Swords will testify that Walgreens and its pharmacists have been threatened or sued by a number of physicians for failing to fill oxycodone prescriptions.

Mr. Swords will explain Walgreens' voluntary decision to discontinue all Schedule II dispensing at the Pharmacies and five other Florida pharmacies. Mr. Swords will testify that, with the support of the Company's most senior management, Walgreens' created a new

department—the Department of Pharmaceutical Integrity—with broad authority to coordinate and supervise the Company's compliance efforts. Mr. Swords will testify that Walgreens has continued to make enhancements to its policies, procedures and technology systems to help prepare it to deal with the next diversion threat.

Mr. Swords will explain how, pursuant to DEA regulations, some Walgreens pharmacies make use of a "central fill pharmacy" for filling certain prescriptions. He will explain the process by which a prescription comes into a retail pharmacy, how a determination is made whether that prescription should be centrally filled, and how a central fill order is processed and ultimately dispensed to a patient. He will testify that under paragraph 4(f) of the 2011 MOA, Walgreens agreed to maintain dispensing records electronically and to make them available "within a reasonable time" of any DEA request, and will explain how Walgreens complies with that requirement. Mr. Swords will testify that each prescription that is centrally filled is tracked electronically, that the label and exterior packaging of all centrally filled drugs contain unique identifiers indicating that the drug was centrally filled, and that Walgreens' computer system enables pharmacists to easily identify whether any given prescription was centrally filled. Mr. Swords will testify that Walgreens' corporate office can, within a matter of hours, make available for inspection a complete list of prescriptions that have been centrally filled for any given retail pharmacy. Mr. Swords will testify that physically marking a hard copy prescription with the notation "CENTRAL FILL" could potentially result in pharmacies maintaining inaccurate records in violation of DEA regulations and state laws, because refills based on that prescription may not be centrally filled. He will testify that the Company's central fill pharmacy in Orlando, FL voluntarily stopped filling prescriptions for controlled substances on November 1, 2012, and that the Company has never used central fill pharmacies for filling Schedule II drug prescriptions presented to retail pharmacies.

Mr. Swords will describe how paragraph 4(b) of the 2011 MOA requires Walgreens to utilize data provided by NTIS to verify that prescribers of controlled substances have active, valid DEA registration numbers, and how that system operates. Mr. Swords will explain how Walgreens uses data from NTIS and other sources and will rebut DEA's allegations that its verification system was inadequate. Mr. Swords will testify about other technological enhancements Walgreens is implementing to assist its pharmacists in consistently exercising their professional judgment.

#### 2. Tasha Polster, Director of Pharmaceutical Integrity

Tasha Polster will describe her new role as Director of Pharmaceutical Integrity at Walgreens, her department's responsibility for oversight of controlled substances handling at pharmacies and distribution centers, and will describe the state-of-the-art technological tools and policy changes that Walgreens has implemented to make sure that Walgreens is at the forefront of preventing diversion of controlled substances.

Specifically, Ms. Polster will explain the initiatives she has pursued and implemented since she assumed her role along with other ongoing anti-diversion activities. She will testify about enhancements to the Good Faith Dispensing procedures that she spearheaded to help pharmacists exercise their professional judgment, and will describe new specialized policies and procedures she developed and implemented for pharmacists filling certain drugs with a higher than normal risk of diversion (such as the Target Drug Good Faith Dispensing Checklist, *see* Exhibit 244).

Ms. Polster will also explain the technological enhancements that Walgreens has implemented to prevent the events of 2010 and 2011 from recurring, including functionality added to Walgreens' computerized systems to perform advanced statistical analyses on

pharmacy orders and detect potential diversion problems. She will testify that such systems utilize quantity ceilings and thresholds to prevent the distribution centers from shipping greater quantities of controlled substances to pharmacies. She will testify that Company procedures will not permit Walgreens pharmacies to receive shipments above particular ceiling levels until an appropriate review of the order occurs. She will testify that Walgreens has implemented state-of-the-art reporting and monitoring tools that allow her team and other key personnel in the Company to monitor for new trends potentially indicative of diversion, and how she intends to use those tools. She will testify that the Company uses these tools to verify that its pharmacists are properly exercising their professional judgment and satisfying their corresponding responsibility. Ms. Polster may perform a demonstration of these technological tools for the Court using a laptop with sample data. Ms. Polster will describe additional tools Walgreens is implementing in its next generation pharmacy computer systems. Ms. Polster will also testify about how Walgreens integrates NTIS into its computer systems to help pharmacists verify the status of DEA registration numbers.

Finally, based on her decades of experience as a pharmacist, Ms. Polster will describe how DEA's new approach to regulating controlled substances is changing the traditional relationship between pharmacists and physicians, and how Walgreens has restructured its organization and rewritten its policies to address those changes.

# 3. Joanna Shepherd-Bailey, Ph.D., Associate Professor of Law at the Emory University School of Law

Dr. Shepherd-Bailey will testify about her education, training, experience and responsibilities, and will offer her expert opinions based on her analysis of prescription dispensing data about, among other things, the flaws in DEA's analyses and contentions relating to: (1) DEA's comparison of oxycodone dispensed at certain Walgreens pharmacies with the

oxycodone dispensed at other retail pharmacies, including the average U.S. retail pharmacy, the average Florida retail pharmacy, the average Florida Walgreens pharmacy, the average Walgreens pharmacy in particular counties, top oxycodone purchasers in Florida and in the U.S., and the top Walgreens pharmacy purchasers of oxycodone; (2) DEA's evaluation of volume increases in oxycodone dispensing, including increases following the change in Florida Law in mid-2010, see, e.g., Gov.'s Walgreens #04727 PHS at 7 (Proposed Testimony of DPM Susan Langston); Gov.'s Walgreens #06997 PHS at 4-5 (same); (3) DEA's assessment of the extent to which oxycodone volume redirected as a result of Florida policy changes was illegitimate; (4) DEA's discussion of customer and prescriber red flags in the context of the dispensing data, including, among other red flags identified by DEA, prescriber patterns, patient and prescriber distance, and method of payment; (5) DEA's analysis of oxycodone dispensing patterns to outof-state customers; (6) DEA's analysis of the dispensing patterns for oxycodone prescriptions written by prescribers without valid DEA registrations; (7) the applicability of the chi squared methodology proffered by DEA's witness, Mary E. Chmielewski, Ph.D., Senior Personnel Psychologist, Research & Analysis (HRN), Human Resources Division; and (7) the efficacy of the controls implemented by Walgreens by reference to prescriber and dispensing patterns.

Dr. Shepherd-Bailey will also testify about the legitimate reasons that volumes of oxycodone dispensed from a given pharmacy could increase over time, why such volumes could be substantially higher for some pharmacies than for the average pharmacy and would not necessarily raise a red flag. Dr. Shepherd-Bailey may also provide testimony in rebuttal to any additional quantitative or statistical analyses introduced by DEA and its witnesses.

#### 4. Sunil J. Panchal, M.D.

Dr. Panchal will testify to his background, education and training, including, but not limited to, that he received his medical degree from Albany Medical College of Union

University in Albany, New York, performed a residency in anesthesiology at Northwestern University, and then completed a fellowship in pain management at the University of Illinois in Chicago. Dr. Panchal previously served as the Co-Director of the Chronic Pain Service as well as the Director of the Multidisciplinary Pain Fellowship Training Program at Johns Hopkins University, and subsequently as Director, Division of Pain Medicine at the Joan and Sanford I. Weill Medical College of Cornell University. More recently, Dr. Panchal was an Associate Professor in the Departments of Oncology and Anesthesiology and Director of Intervention Pain Medicine at the H. Lee Moffitt Cancer Center and Research Institute of the University of South Florida College of Medicine in Tampa, Florida. Dr. Panchal has also held leadership positions in many professional societies, including the Committee for Pain Medicine for the American Society of Anesthesiologists, and on the Board of Directors for the American Academy of Pain Medicine. Dr. Panchal is currently the President of the National Institute of Pain, a private, nonprofit corporation with offices in Lutz, Florida, where he treats patients who are suffering from acute or chronic debilitating pain.

Dr. Panchal will offer his expert opinion about acute and chronic pain conditions and treatment that is within the usual course of professional practice, address DEA's mistaken allegations that specific prescriptions or prescribing patterns should have raised "red flags." He will rebut Prof. Doering's proposed expert testimony and explain the appropriate medical treatment of pain and the role of opioids in pain management in this context. He will testify that oxycodone is a legitimate choice for treating pain when opioid therapy is indicated. He will also describe the training and education that doctors receive regarding the use of opioids and the development of pain medicine as a specialty, and thus why certain types of prescriptions DEA alleges are problematic should not necessarily raise red flags. Dr. Panchal will testify about the

range of training and expertise in pain management among doctors and that legitimate well-intentioned doctors will disagree on the proper treatment for pain, including about what medication, if any, should be prescribed and what dosage. He will testify that physicians who have a more limited knowledge base with respect to alternative treatments for pain management, are still within the scope of their medical practice to rely entirely on medication and medication management for pain, including the use of opioids.

Dr. Panchal will testify that volumes of oxycodone alone, either prescribed by a physician or dispensed by a pharmacy are an insufficient basis for concluding that diversion is occurring. He will explain how a prescription for a legitimate medical purpose within the usual course of professional practice may be for the same number of dosage units as an illegitimate prescription, and that the number of dosage units should not necessarily be a red flag to a pharmacist. Dr. Panchal will explain that it is commonplace for physicians who manage pain primarily with medications to increase the dose in response to the development of tolerance, so the number of dosage units per patient filling prescriptions at a pharmacy may increase, in some cases quite dramatically, over time. Dr. Panchal will further testify that other alleged red flags cited by DEA are not reliable indicators of diversion or treatment outside the usual course of professional practice.

Dr. Panchal will explain that although pharmacists have a corresponding responsibility under the regulations, in many cases pharmacists are not well equipped to review and assess physicians' diagnoses and treatment decisions. In a number of circumstances, pharmacists lack sufficient knowledge, training or background to identify certain prescribing decisions as "red flags" or to second-guess the prescribing decisions of physicians, and may have significant difficulty determining whether narcotics, including oxycodone, are being diverted into other than

legitimate medical channels by patients. As DEA has previously acknowledged in its public statements, pharmacists and law enforcement officers may not be qualified to evaluate the prescriptions for the purpose of determining whether the number of dosage units, dosage strength and active ingredients are appropriate, and do not have the expertise to contravene the treating physician's decision to prescribe a particular drug regimen. Dr. Panchal will testify that a pharmacist cannot apply a one-size-fits-all rule to refuse to fill prescriptions, and that DEA's attempt to categorize and label certain circumstances as red flags could end up preventing legitimate patients from obtaining needed therapy.

Dr. Panchal will testify that, following DEA's effort to crack down on opioids, many of his legitimate patients have had difficulty filling prescriptions for opioids, including at Walgreens pharmacies. Dr. Panchal will testify that his patients have been told by pharmacists at local pharmacies near his office that they will have to wait a week to fill their prescriptions because the store is out of stock. Waiting a week is simply not an option for patients suffering from severe pain. Therefore, pharmacies that are able to secure adequate provisions of opioids have seen increasing demand from legitimate patients to fill opioid prescriptions.

#### 5. David Brushwood, R.PH, J.D., University of Florida College of Pharmacy

David Brushwood is a professor of Pharmaceutical Outcomes and Policy at the University of Florida College of Pharmacy. He is a graduate of the schools of pharmacy and law at the University of Kansas and has practiced as both a pharmacist and as an attorney. Professor Brushwood will describe his background, education and training as a pharmacist, attorney and professor of pharmacy.

Professor Brushwood will offer his expert opinion about the scope of professional responsibilities of a pharmacist, the Florida state law obligations of a pharmacist, and a pharmacist's corresponding responsibility under the regulations. He will describe how

pharmacists are educated about their responsibilities and the historic means by which pharmacists exercised their corresponding responsibility, particularly efforts to identify forged or stolen prescriptions.

Professor Brushwood will describe the additional burdens placed on pharmacists following the Florida pain clinic legislation in 2010. He will testify that Florida pharmacies were faced with an influx of new patients (often coming from new doctors) for whom they had no prior patient history or experience. He will testify that although some red flags may be immediately apparent to a pharmacist (*i.e.*, evidence that a prescription is forged) patterns of prescribing indicative of diversion, or other factors that may indicate that a prescription is outside the usual course of medical treatment, take time to become apparent. Professor Brushwood will testify that in Florida generally, and at the Pharmacies specifically, the number of dosage units dispensed increased following the legislation and then declined as patterns developed, pharmacists identified potential diversion, and controls were implemented that prevented improper prescriptions from being filled. Professor Brushwood will also testify that following the pain clinic legislation, the traditional paradigm of doctors and pharmacists as partners was altered, and pharmacists for the first time needed to more rigorously question the treatment decisions of physicians.

Professor Brushwood will testify that the evidence of the Pharmacies refusing to fill prescriptions shows that the pharmacists were wrestling with the difficult circumstances and exercising their professional judgment. Professor Brushwood will describe the difficult judgments and considerations that may factor in to a pharmacist's decision whether or not to fill a prescription for pain medication. Professor Brushwood will also testify about the reasonableness of the controls Walgreens and the Pharmacies implemented to help uncover

illegitimate prescriptions. Professor Brushwood will testify about Walgreens' Good Faith Dispensing Policy and that it provides Walgreens pharmacists with further guidance to help them exercise professional judgment in a matter that will detect and prevent potential diversion.

Dr. Brushwood will also respond to testimony offered by Professor Doering. He will respond to Professor Doering's testimony regarding so-called "red flags" and the steps a pharmacist may take in response to identifying such red flags. Professor Brushwood will explain what may or may not be a red flag, and moreover, that the presence of one or more red flags does not necessarily mean that a pharmacist cannot ethically and within the reasonable range of professional judgment dispense medication to the patient.

# 6. Cheryl Creek, Director, Operations Optimization - Health and Wellness Initiatives

Cheryl Creek is the Director, Operations Optimization – Health and Wellness Initiatives (formerly titled the Manager of Pharmacy Training) at Walgreens' Corporate Headquarters. Ms. Creek will describe the enhancements that were made to Walgreens Good Faith Dispensing Policy and other measures following Florida's legislative changes in 2010.

Ms. Creek will testify that she is the liaison between the Learning & Development Team and the Operations Team at Corporate Headquarters. In this capacity, Ms. Creek works closely with the Walgreens policy team to develop and modify pharmacy policies and procedures, and to assist in implementing these policies within the Company. Ms. Creek will also describe the role that Pharmacy Supervisors and District Managers are expected to play in monitoring local conditions, establishing best practices and seeing that pharmacists receive appropriate training.

Ms. Creek will describe Walgreens' Good Faith Dispensing Policy and how it has developed over time to help pharmacists properly exercise their professional judgment. Ms. Creek will describe updates to the Good Faith Dispensing Policy in June 2011 and June 2012,

how these updates improved the policy, and why those improvements were made. Ms. Creek will further testify how pharmacists are trained on good faith dispensing, including, but not limited to, describing training for pharmacists on the updates to Good Faith Dispensing Policy that occurred in October 2011 and July 2012.

### 7. Terry Gubbins, Market Pharmacy Director, Markets 3 and 28

Terry Gubbins will explain his role as the Market Pharmacy Director for Markets 3 and 28, which include Hudson, FL and Oviedo, FL. Mr. Gubbins will describe the issues his pharmacies began facing in 2010, the proactive steps that were taken to address the challenges brought by an increase in patients seeking oxycodone, specific controls that were implemented at Walgreens #03629 and #06997, and the lack of guidance from DEA.

Specifically, Mr. Gubbins will testify to his background, education, training, and his participation in professional associations, specifically as the president-elect of the Florida Pharmacy Association. He will testify about his 30 years of experience at Walgreens as a pharmacist, store Pharmacy Manager, District Pharmacy Supervisor, Divisional Director, and his current role as Market Pharmacy Director for Walgreens Market 3 in Florida. Mr. Gubbins will testify about the role of market and district supervision of Walgreens stores in Florida, and in particular the role of supervisors in training store pharmacists and technicians, monitoring store dispensing activities, and ensuring compliance with applicable state and federal laws and regulations.

Mr. Gubbins will testify that in late 2010, following changes in Florida law, stores in his market began to see an increase in patients presenting prescriptions for oxycodone. He will testify about competitors in the marketplace who determined that it would be easier to refuse to dispense any oxycodone rather than trying to determine which patients were presenting legitimate prescriptions. This trend caused more patients to present prescriptions at Walgreens

stores where pharmacists were looking for potential "red flags" and were attempting to exercise their judgment properly by filling certain prescriptions while regularly refusing to fill others. Mr. Gubbins will also testify that store pharmacists routinely faced threats and complaints from both patients and doctors as a result of their questioning of—and refusals to fill—prescriptions for oxycodone, and he will testify that Walgreens received daily telephone complaints based on the stores' refusals to fill oxycodone.

Mr. Gubbins will testify about the steps taken, from mid-2010 through 2012, at the market and district levels to assist the pharmacists and stores in identifying suspicious prescriptions and preventing diversion. These measures included reinforcing Walgreens' Good Faith Dispensing Policy, the use of professional judgment, and the pharmacist's "corresponding responsibility"; re-training pharmacists; devising detailed, localized action plans and best practices for the dispensing of oxycodone; assessing dispensing data and feedback from individual stores; conducting supervisory visits to stores to observe dispensing practices and meet with store personnel; and holding regular meetings with store personnel, store Pharmacy Managers and Loss Prevention personnel to discuss ongoing dispensing issues. Mr. Gubbins will discuss an external Continuing Education program that he implemented in his markets that addressed issues regarding how pharmacists should exercise their professional judgment. He will testify that he instructed pharmacists within his market to visit newly opened pain clinics to assess their legitimacy. He will testify that he instructed his pharmacy supervisors to stress the importance of the corresponding responsibility to the pharmacists, to monitor oxycodone dispensing levels, and to take additional basic security measures such as keeping the parking lots clear of loiterers. Mr. Gubbins will testify that the pharmacies were concerned about red flags and thus were refusing to fill many prescriptions; indeed, Pharmacy Supervisors would spend hours a day just responding to complaints filed through Walgreens' corporate complaint system.

# 8. Doug Lemmons, Divisional Loss Prevention Operations Director

Mr. Lemmons will explain his current role as the Divisional Loss Prevention Operations Director for Walgreens and how his department assists with compliance and investigating theft and losses. Mr. Lemmons will describe the steps Loss Prevention took beginning in 2010 and continuing through the present to help equip pharmacies to properly respond to increased demand for oxycodone and reduce oxycodone volume to where it is today.

Specifically, Mr. Lemmons will testify that in 2010 when the oxycodone dispensing numbers initially began to increase, Walgreens responded at the district and market level. Mr. Lemmons will describe efforts made by Loss Prevention, including meeting with pharmacists and Pharmacy Supervisors to assess the problem, providing assistance to Pharmacy Supervisors to help put together Action Plans to assist pharmacists in exercising their professional judgment, and meeting with law enforcement groups to discuss solutions. Mr. Lemmons will describe the role of Walgreens' corporate headquarters in addressing the higher oxycodone dispensing numbers in Florida, including the timing of when corporate headquarters first became aware of the problem and the assistance that Loss Prevention provided to Pharmacy Supervisors in implementing measures to respond to the issues. Mr. Lemmons will describe the nature and evolution of the Focus on Profit program and the development of the Focus on Compliance.

Mr. Lemmons will describe fact-finding visits he made with Walgreens' Director of HealthCare Loss Prevention to high dispensing stores in Florida. He will testify that during these visits, he met with the pharmacists and Pharmacy Supervisors, and will describe the discussions about the best practices that they were implementing, and how he took that information back to corporate headquarters for analysis.

Mr. Lemmons will testify about a meeting he and a District Loss Prevention Manager had

with a DEA investigator during which they discussed Walgreens' practices for submitting information to DEA. Mr. Lemmons will testify that the investigator told them to stop faxing copies of the prescriptions Walgreens was refusing to fill because the stores were overloading DEA. (The fact that Walgreens' pharmacies were refusing to fill so many oxycodone prescriptions is relevant to whether such pharmacies were exercising their responsibility to carefully review such prescriptions.) He will further testify that the investigator was asked whether there was anything additional that Walgreens should be doing, and the investigator stated there was not.

#### 9. John Rossing, Manager, Results Financial Planning and Analytics

John Rossing is the Manager of Results Financial Planning and Analytics at Walgreens' Corporate Headquarters. In paragraph 8 of its Prehearing Statement for Walgreens #04727, DEA indicates that it intends to have Andrea Cohen testify about any bonuses that she may have received while working at Walgreens #04727. Mr. Rossing is prepared to testify in rebuttal, specifically that prescription volume is one of several factors in determining bonuses, and a new prescription may contribute only a few cents to a pharmacist's bonus—if DEA intends and is permitted to introduce testimony on this point.

## 10. Kevin Pepkowski, Store Manager, Walgreens #03933

Mr. Pepkowski is the store manager of Walgreens #03933 in Coral Springs, FL. He will testify that on January 11, 2013, Susan Langston (Diversion Program Manager, DEA Miami) informed him, after reviewing Walgreens' Target Good Faith Dispensing Checklist, that Walgreens should not rely on checklists to prevent diversion and should instead rely on pharmacists exercising their professional judgment. Mr. Pepkowski will testify how this instruction is yet another instance of the "mixed messages" given to Walgreens by DEA: after complaining in 2012 that pharmacists exercising their professional judgment had allowed

oxycodone dispensing to increase improperly, Walgreens implemented new requirements further limiting the types of oxycodone prescriptions that could be filled by a pharmacist exercising his/her professional judgment. But Ms. Langston has now apparently come full circle and is instructing Walgreens now to eliminate these measures and return to same system of oversight on dispensing that she previously criticized.

#### 11. Jennifer Strickland, PharmD, BCPS

Dr. Jennifer Strickland will testify to her background, education and training, including, but not limited to, that she received a doctor of pharmacy degree with the highest honors from the University of Florida College of Pharmacy; that she is board certified in pharmacotherapy ("BCPS) by the Board of Pharmaceutical Sciences; and that she was the pharmacist for the Pain and Palliative Care Service at the H. Lee Moffitt Cancer Center for six years and has comanaged pain, psychiatry, and addiction clinics in the past.

Dr. Strickland will offer her expert opinion about the role of medications in palliative medicine and chronic pain management. Dr. Strickland will describe the physician's role in prescribing pain medication and the pharmacist's corresponding responsibility under DEA regulations. She will testify that prior to the pain clinic issue, in all but the most exceptional cases, physicians and pharmacists were allies in the fight against diversion and worked together to combat diversion, most frequently from stolen, forged or altered prescriptions. Dr. Strickland will explain how the abuse of prescription pain medications by individuals, facilitated in some cases by unscrupulous doctors and pain clinics, particularly in Florida, has altered the traditional partnership between doctor and pharmacist and led to a re-assessment of the proper role of the pharmacist. Dr. Strickland will discuss this changing paradigm in the context of the changes in Florida law and the impact on pharmacists. Dr. Strickland will explain that there is limited guidance from DEA or any other organization in this area and that pharmacists across the State

were struggling to properly address the issues that resulted from Florida's legislative changes. She will note that the challenges faced by certain pharmacies attempting to make these difficult judgments were compounded by other Florida pharmacies' decisions to discontinue dispensing certain oxycodone medications altogether, which had the effect of concentrating a larger percentage of oxycodone patients at Florida pharmacies (including the Pharmacies) that were willing to wrestle with the increasingly difficult task of making professional judgments about the legitimacy of prescriptions issued by physicians with valid DEA registrations. Dr. Strickland will testify about Walgreens' Good Faith Dispensing Policy, specifically that it provides Walgreens pharmacists with appropriate guidance to prevent and detect potential diversion.

Dr. Strickland will also respond to testimony offered by Professor Doering and describe the steps a pharmacist may take in response to identifying such red flags. Dr. Strickland will also describe how a pharmacist should exercise his or her professional judgment when confronted with so-called red flags.

### 12. Kristie Provost, Director, Strategic Planning & Analytics, Loss Prevention

Kristie Provost will explain her role as Director of Loss Prevention Strategic Planning & Analytics at Walgreens and will describe the historical efforts of Walgreens' Loss Prevention department to help detect and investigate potential diversion, how that role has expanded over time to respond to new threats, and the new technological tools that are now in place to ensure that the Company proactively detects and responds to potential diversion.

Ms. Provost will explain the data trends that emerged in 2010 through 2012 regarding the quantity of oxycodone and other controlled substances dispensed from the Pharmacies. With respect to oxycodone, she will describe the increase that began in 2010 and the rapid subsequent decline in 2011. She will describe the analytical tools that were formerly and are currently

available to Loss Prevention and other Walgreens departments to collect the data and monitor trends.

Ms. Provost will testify that she has acted as a technical consultant during the development of the software and reporting tools used in Walgreens' anti-diversion efforts, including Walgreens' suspicious order monitoring systems, data monitoring tools, and new dashboard monitoring systems. If necessary, Ms. Provost can describe formulas used in, and other technical specifications of, the software and tools. She will also authenticate charts and other data as necessary.

#### 13. William Schwartz, DEA Diversion Investigator

Mr. Schwartz will be asked to testify about his experience as a DEA Diversion Investigator and his role with respect to Walgreens stores in Florida. He will be asked to testify about meetings, interactions, and communications he had with Walgreens personnel. In particular, he will be asked to testify about a meeting that occurred on or about August 19, 2011 during which he, Susan Langston (Diversion Program Manager, DEA Miami), and Roger Kernicky (Diversion Investigator) met with Georgia Lehoczky and other Walgreens personnel at DEA's office in Weston, Florida. He will be asked to testify about the discussions that took place at that meeting regarding Walgreens' dispensing practices at its Florida stores. He is expected to testify that he made statements that Walgreens was making good-faith efforts at its stores to prevent the diversion of oxycodone and to comply with DEA regulations and that he did not have concerns about Walgreens' dispensing practices. He will also be asked whether Walgreens personnel requested from DEA information regarding suspicious prescribing doctors, and he is expected to testify that DEA refused to provide such information.

#### 14. Roger Kernicky, DEA Diversion Investigator

In the event that William Schwartz is unavailable to testify, Walgreens will ask Mr. Kernicky to testify in the alternative. Mr. Kernicky's testimony is expected to be substantially similar to that of Mr. Schwartz.

#### 15. John Mudri, Mudri Associations Inc.

John Mudri will testify to his background, education and training, including, but not limited to, his experience as a Chief, U.S. Drug Enforcement Administration; DEA Supervisory Investigator; DEA Instructor for Diversion (National, Ohio, Michigan and Florida); Instructor for U.S. Drug Enforcement Administration national domestic drug policy conferences; Instructor at United States Attorney Conferences; Instructor for pharmaceutical industry management conferences; Instructor for medical, pharmaceutical and wholesaler continuing education conferences; Instructor for law enforcement agencies including FBI, Michigan State Police and Maryland State Police; and as a board member of the Florida Board of Pharmacy.

Mr. Mudri will offer his expert opinion regarding Walgreens' due diligence and controls designed to prevent diversion and improper dispensing relative to the kinds of diligence undertaken in the industry. Mr. Mudri will testify about Walgreens' response to the red flags that its pharmacies began identifying in late 2010, at the district and market levels and ultimately by Walgreens' corporate headquarters, including limiting dispensing to defined geographic boundaries, verifying prescriptions, identifying troubling prescription patterns, attempting to reduce volume at its stores, cooperating with local law enforcement, seeking guidance from DEA, providing additional training to pharmacists, and developing and implementing best practices for good faith dispensing. This testimony will rebut evidence from DEA regarding what Walgreens could have and should have done to prevent diversion.

### B. Witnesses Whose Testimony Is Applicable Only To Walgreens #03629

#### 16. Caren Cohalla, Pharmacy Manager, Walgreens #03629

Caren Cohalla will testify about her over 15 years of experience at Walgreens, including as the Pharmacy Manager at Walgreens #03629 in Hudson, Florida. Ms. Cohalla will testify that although her store dispensed what DEA identifies as a significant volume of oxycodone, she and her pharmacy technicians worked extremely hard every day under very difficult circumstances to ensure the pharmacists exercised their professional judgment on every prescription, and that many of the controls that were implemented at Walgreens #03629 to prevent diversion formed the foundation of Walgreens' Good Faith Dispensing Policy.

Specifically, Ms. Cohalla will testify that the number of dosage units dispensed from Walgreens #03629 does not tell the complete story. She will testify that in addition to the influx of patients following the legislative changes, numerous surrounding pharmacies refused to dispense oxycodone at all, driving significant numbers of patients to Walgreens #03629. She will testify that before Florida's PDMP became operational, she required new patients to submit prescription histories and existing patients to explain excessive time gaps between prescriptions. She will testify that her store developed a number of additional protocols and guidelines to prevent diversion, including: not filling for customers with a Naples address; not filling for patients with addresses in a county that did not abut Pasco County; reducing the volume of dosage units per prescription; and not filling certain combinations of drugs or prescriptions without an extended release formulation. She will testify that every time Walgreens #03629 implemented a new control, the doctors and patients would come up with another scheme to circumvent it.

Ms. Cohalla will testify about the significant volume of oxycodone prescriptions her pharmacy refused to fill each day. She will testify that they received many complaints every day

based on those refusals to fill. She will testify that she and her pharmacy technicians worked hard to do the right thing, consistent with limited guidance from DEA. She will testify that she worked closely with local police to patrol the parking lots and to help prevent diversion. Despite help from local law enforcement, Ms. Cohalla will testify that she repeatedly sought guidance from DEA and the State of Florida and received no assistance at all.

Ms. Cohalla will also testify regarding her understanding of the facts related to DEA's allegation that Walgreens #03629 continued to fill oxycodone prescriptions for a customer about whom the store had at one time called the police because they suspected a fraudulent prescription. She will also testify regarding her understanding of the facts related to DEA's allegation that Walgreens #03629 filled a prescription issued by Dr. Pritchard using an incorrect label. She will also testify that, contrary to the allegations implied in DEA's proposed testimony (see Gov.'s Walgreens #03629 PHS at 13 (proposed testimony of Investigator Flagg); id. at 6-7 (proposed testimony of Susan Langston)), Walgreens #03629 did not fill an unusual number of oxycodone prescriptions for out-of-state patients.

### 17. Terry Collins, District Pharmacy Supervisor, District 227 (Tampa North)

Terry Collins will describe his experience as the District Pharmacy Supervisor, including his oversight of Walgreens #03629. Mr. Collins will describe the steps that his pharmacies took to prevent and detect diversion and the policies and procedures that were implemented. He will testify that specifically with respect to Walgreens #03629, although there was a high volume of oxycodone dispensing, he is confident that the store was working diligently to prevent diversion and was adhering to the good faith dispensing guidelines and exercising professional judgment in the face of extremely difficult circumstances.

Specifically, Mr. Collins will testify that in late 2010 he started seeing increases in oxycodone dispensing and started seeing new clientele in his pharmacies. This caused him to

begin to work with his pharmacies to develop guidelines on proper dispensing of controlled substances. He will testify that the guidelines began as oral advice and ultimately became written guidelines. Mr. Collins will discuss disciplinary action taken against a pharmacist that he did not feel was adequately exercising his professional judgment after these additional measures were put in place.

Mr. Collins will testify that the initial anti-diversion controls included limiting the quantity of dosage units that could be dispensed per prescription and prohibiting dispensing based on certain geographic distances or variables. Mr. Collins will testify that patients and doctors quickly adapted and found ways to circumvent those guidelines, including obtaining ID cards for vacant or empty houses and changing the quantities or drug combinations, making it difficult for pharmacists to identify illegitimate prescriptions. Mr. Collins will describe the arguments, confrontations and complaints that his pharmacists and pharmacies received based on their refusals to dispense to certain customers. Mr. Collins will testify that nearly all of his pharmacists have felt threatened by customers and that many attempted to avoid dispensing controlled substances at all, or would carry limited quantities in stock.

Finally, Mr. Collins will testify regarding how some prescriptions at his stores are centrally filled at Walgreens' Orlando central fill pharmacy, and how Walgreens' system tracks which prescriptions were filled there.

# 18. Amy Spiehs-Hicks, District Loss Prevention Manager, District 198 (Tampa West)

Amy Spiehs-Hicks will testify about her role as a Loss Prevention Manager, including her direct involvement with Walgreens #03629. Specifically, Ms. Spiehs-Hicks will testify that Walgreens #03629 was extremely diligent in its efforts to prevent diversion. She will testify about neighboring stores that closed or stopped dispensing oxycodone, and the impact on Walgreens #03629. Ms. Spiehs-Hicks will testify that she had a cooperative relationship with Pasco County law enforcement and will describe the cooperative efforts at Walgreens #03629, including efforts that resulted in numerous arrests. Ms. Spiehs-Hicks will also describe other district-wide efforts to combat oxycodone diversion, including the dispensing guidelines and action plans that she helped create to guide stores. She will testify that the PDMP system has helped Walgreens pharmacies prevent diversion of controlled substances.

## 19. Bryon Wheeldon, Market Loss Prevention Director, Market 3

Bryon Wheeldon will testify about his current role as the Market Loss Prevention Director for Walgreens Market 3, which includes Tampa, Sarasota, and Naples, Florida and their surrounding areas. Mr. Wheeldon will describe the nature of Loss Prevention at Walgreens; the historic cooperative relationship between the pharmacies in his market and the local DEA; the challenges that pharmacies in his market faced beginning in mid-2010; and the steps his department took to help prevent the diversion of controlled substances and reduce the volume of oxycodone shipments from the Jupiter Facility.

Specifically, Mr. Wheeldon will testify that in late 2010, following changes in Florida law, pharmacies in Market 3 began to see an increase in patients with prescriptions for oxycodone. Mr. Wheeldon will testify that the Loss Prevention team in Market 3 supported the Pharmacy Supervisors and pharmacists in identifying issues that were occurring in the

pharmacies and taking steps to ensure good faith dispensing practices were being utilized. He will also testify about requests for guidance from DEA and DEA's response that they could not provide guidance about what prescriptions to fill. He will testify about the work he undertook with his counterparts in Loss Prevention and with Pharmacy Directors to prepare a Florida-specific Focus on Compliance.

Mr. Wheeldon will describe the evolution of the Focus on Compliance and will testify that Walgreens surveyed top dispensing stores in Florida in June 2012. He will testify that the District Loss Prevention Managers and Pharmacy Supervisors were required to visit stores in their district which had seen the greatest increase in pharmacy sales to review proper pain medication dispensing policies, procedures and compliance.

Mr. Wheeldon will further testify that competitors in the marketplace began refusing to dispense any oxycodone at all, which caused dispensing to increase at Walgreens pharmacies, including Walgreens #03629, even though pharmacists were enforcing the Good Faith Dispensing Policy and regularly turning prescriptions away. Mr. Wheeldon will describe how he visited stores who were dispensing high volumes of oxycodone, and will describe specific instances he observed where pharmacists refused to fill prescriptions they were uncomfortable with.

Mr. Wheeldon will also testify to his market's relationship and historic partnership with DEA. He will testify that in approximately 2003 or 2004, he proposed to DEA that it, other law enforcement agencies and loss prevention personnel for retail pharmacies have quarterly meetings to share information and discuss current issues and challenges in the industry. Mr. Wheeldon told DEA that Walgreens would provide the location and handle the logistics, but that

the invitations should be on DEA letterhead, so that it did not appear to Walgreens' competitors to be a "Walgreens meeting."

Mr. Wheeldon will testify that Kenneth Boggess of DEA took the lead on these meetings, and they have been very successful. Mr. Wheeldon will testify that these meetings gave DEA the opportunity to raise issues with registrants, and that until DEA executed administrative warrants at Walgreens facilities, Walgreens participated in those meetings.

Mr. Wheeldon will also testify that in March 2012, he contacted Mr. Boggess and asked if DEA wanted to conduct any training with pharmacists (Walgreens and other retailers) to better address the oxycodone issues in Florida. Mr. Wheeldon again offered to provide meeting space. Mr. Wheeldon will testify that Mr. Boggess told him that he did not have concerns about Walgreens, that he was aware of Walgreens' efforts and partnership and that Walgreens had initiated the DEA/industry meetings. Mr. Wheeldon will testify that he asked whether there was anything else Walgreens should be doing to help prevent diversion, and Mr. Boggess said that he had no concerns about Walgreens and declined to conduct the training proposed by Mr. Wheeldon.

Mr. Wheeldon will testify that Walgreens made a presentation to Central Florida law enforcement officials in May 2011 at a meeting supported by the Central Florida Drug Enforcement Strike Force. Mr. Wheeldon will testify that he made a presentation focused on issues in the dispensing of pain medication.

### C. Witnesses Whose Testimony Is Applicable Only To Walgreens #04727

### 20. Georgia Lehoczky, Market Pharmacy Director, Market 6

Georgia Lehoczky will explain her role as the Market Pharmacy Director for Market 6, which includes Ft. Pierce and Palm Beach. Ms. Lehoczky will describe the issues her pharmacies began facing in 2010, the proactive steps that were taken to address the challenges

brought by an increase in patients seeking oxycodone, specific controls that were implemented at Walgreens #04727 and the lack of guidance from DEA.

Specifically, Ms. Lehoczky will testify to her background, education, and training, as well as her 25 years of experience at Walgreens as a pharmacist, store Pharmacy Manager, District Pharmacy Supervisor and her current role as Market Pharmacy Director for Walgreens Market 6 in Florida. Ms. Lehoczky will testify about the role of market and district supervision of Walgreens stores in Florida, and in particular the role of supervisors in training store pharmacists and technicians, monitoring store dispensing activities, and ensuring compliance with applicable state and federal laws and regulations.

Ms. Lehoczky will testify that in late 2010, following changes in Florida law, stores in her market began to see an increase in patients presenting prescriptions for oxycodone. She will testify about competitors in the marketplace who were refusing to dispense any oxycodone, which caused dispensing to increase at Walgreens stores where pharmacists were enforcing the Good Faith Dispensing Policy and regularly turning prescriptions away. Ms. Lehoczky will also testify that store pharmacists routinely faced threats and complaints from both patients and doctors as a result of their questioning of—and refusals to fill—prescriptions for oxycodone, and she will testify that Walgreens received daily telephone complaints based on her stores' refusals to fill oxycodone.

Ms. Lehoczky will testify about the steps taken, from late 2010 through 2012, at the market and district levels to assist the pharmacists and stores in identifying possible red flags and suspicious prescriptions and preventing diversion. These measures included reinforcing Walgreens' Good Faith Dispensing Policy, the use of professional judgment, and the pharmacist's "corresponding responsibility"; re-training pharmacists; devising detailed, localized

action plans and best practices for the dispensing of oxycodone (including an October 2011 "Market Action Plan/Guidelines for CII Dispensing" document she prepared); assessing dispensing data and feedback from individual stores; conducting supervisory visits to stores to observe dispensing practices and meet with store personnel; and holding regular meetings with store personnel, store Pharmacy Managers and Loss Prevention personnel to discuss ongoing dispensing issues. Ms. Lehoczky will further testify about how Market and District Supervisors partnered with their Loss Prevention counterparts to evaluate oxycodone dispensing by stores and implement these various responsive measures. She will testify that, as a result of these measures, oxycodone dispensing volumes declined for stores in her market in late 2011 and early 2012.

Ms. Lehoczky will testify specifically about Walgreens #04727 located in Ft. Pierce, Florida, and that she and her District staff took a number of proactive steps to reduce oxycodone dispensing and to prevent diversion. Ms. Lehoczky will also testify about her interactions with local law enforcement and DEA personnel. In particular, she will testify that on or about August 19, 2011, she and other Walgreens personnel met with Susan Langston (Diversion Program Manager, DEA Miami), William Schwartz (DEA Diversion Investigator) and Roger Kernicky (Diversion Investigator) at DEA's office in Weston, Florida. She will testify as to discussions at that meeting regarding Walgreens' dispensing practices, DEA's own best practices recommendations (which she and Walgreens personnel subsequently distributed to stores), and DEA's refusal at that meeting to give Walgreens any information regarding suspicious prescribing doctors. Ms. Lehoczky will further testify that at that meeting, the two DEA Diversion Investigators indicated that they were supportive of the anti-diversion efforts Walgreens was making at its stores in confronting the oxycodone issue and did not have

concerns about Walgreens' dispensing practices. She will also testify as to additional discussions she had with Ms. Langston pertaining to Walgreens, including, among other topics, DEA registrations for stores in Florida. And she will testify that she invited Ms. Langston and other DEA personnel to attend multiple internal Walgreens meetings with pharmacists, and DEA declined to attend.

#### 21. Ed Forbes, Market Loss Prevention Director, Market 6

Ed Forbes will explain his role as the Market Loss Prevention Director for Walgreens Market 6, which includes the West Palm Beach, Florida area. Mr. Forbes will describe the steps taken by Loss Prevention in Market 6 to address the influx of oxycodone prescriptions, including store visits, training and implementation of the Market 6 Action Plan. He will describe how doctors and patients attempted to evade the controls that were implemented, and how the controls ultimately reduced the volume of shipments from the Jupiter Facility.

Mr. Forbes will testify that in late 2010, following changes in Florida law, pharmacies in Market 6 began to see an increase in patients with prescriptions for oxycodone. Mr. Forbes will testify about the historic focus of anti-diversion efforts on fraudulent and forged prescriptions, and how the Florida law changed the focus of anti-diversion efforts. He will testify to the remedial measures the Loss Prevention team in Market 6 took to reduce the high dispensing numbers, including developing an Action Plan for addressing Schedule II dispensing, requiring District Loss Prevention Managers to train the Pharmacy Supervisors and Managers, reviewing dispensing data to assess the issue and conducting investigations into specific stores' dispensing. He will testify that he took specific efforts to reduce the volumes at high-dispensing stores in Market 6, including conducting random visits with the Market Pharmacy Director and auditing the high-dispensing stores, instructing the pharmacists to scrutinize the prescriptions and to aggressively reduce the number of oxycodone prescriptions filled and mandating that the

pharmacists at these stores attach the PDMP profile to all new oxycodone prescriptions.

Mr. Forbes will testify that initial efforts by stores in his market at reducing oxycodone dispensing were successful, but that unscrupulous doctors and patients adapted to circumvent the controls. For example, he will testify that some stores started refusing to fill prescriptions for out-of-state patients and then out of county patients, and that the pain clinics would shift their operations to within the county. Mr. Forbes will testify that pharmacists' refusal to fill oxycodone prescriptions that they believed to be illegitimate caused some customers to become hostile, and that as a result, Walgreens had to hire off-duty police officers to provide safety and security for the employees and customers.

Mr. Forbes will testify to Walgreens' efforts to work with law enforcement to prevent diversion. He will testify that the Florida Department of Law Enforcement singled Walgreens out as being an aggressive and supportive partner in fighting drug diversion. He will further testify to a meeting he, the Market Pharmacy Supervisor and the Pharmacy Supervisors from Market 6 had with DEA in August 2011 during which they discussed best practices and means of identifying fraudulent patients more effectively. He will testify that DEA refused to give out specific information about specific doctors.

# 22. Wesley Rohn, District Pharmacy Supervisor, District 112 (Palm Beach North)

Wesley Rohn will testify about this current role as the District Pharmacy Supervisor for District 112, including his oversight of Walgreens #04727. He will testify about the increase of oxycodone prescriptions at Walgreens #04727, and efforts made to reduce the numbers and detect and prevent diversion of controlled substances.

Mr. Rohn will testify that in late 2010, Walgreens #04727 began seeing an increase in customers with oxycodone prescriptions. He will explain that it took time for them to adjust to

the new patient population, the new doctors writing the prescriptions, and to identify indications of potential diversion. He will testify that he reinforced that pharmacists needed to exercise their professional judgment and take steps to ensure that prescriptions were valid. Mr. Rohn will testify that over time he realized that the dispensing numbers were continuing to increase and that additional steps needed to be taken, and that as a result, he began implementing new controls to try to decrease the number of oxycodone prescriptions being filled. He will further testify that he and the District Loss Prevention Manager visited the store to review the prescriptions that had been filled and to verify that the pharmacists were following the implemented controls. He will describe meetings he had with the pharmacists and pharmacy manager during these visits. He will testify that throughout 2011 he continued to implement additional controls to try to curb the dispensing but that fraudulent patients and doctors would adapt to the new controls and find ways to circumvent them. Mr. Rohn will testify about the effectiveness of controls Walgreens implemented and the significant number of prescriptions that his pharmacists refused to fill, and the resulting complaints from customers.

Mr. Rohn will testify about a meeting he and other members of Walgreens management had with DEA in August 2011. He will testify that he took the information he learned at the meeting and conveyed it to the pharmacists in his district, including at Walgreens #04727, and will further testify that he subsequently scheduled sessions for DEA investigators to train his pharmacists on red flags and how to identify diversion.

Mr. Rohn will describe the events of April 4, 2012 when DEA executed an inspection warrant at Walgreens #04727. He will testify about conversations he had with Susan Langston and Gayle Lane from DEA and Robert Differe from the Florida Department of Health.

Finally, Mr. Rohn will testify regarding how some prescriptions at his stores are centrally filled at Walgreens' Orlando central fill pharmacy, and how Walgreens' system tracks which prescriptions were filled there.

## **D.** Witnesses Whose Testimony Is Applicable Only To Walgreens #06997

## 23. Daniel Heinis, Pharmacy Manager, Walgreens #06997

Daniel Heinis will testify to his current role as the pharmacy manager at Walgreens #06997 in Oviedo, FL. He will testify that in late 2010, following changes in Florida law, his store began to see an increase in patients with prescriptions for oxycodone, including some from the Miami area or out-of-state. In response, his store established a number of limits on oxycodone dispensing, including a geographical service area limited to patients or doctors in Seminole County or Orange County, and other limits on dispensing prescriptions.

Mr. Heinis will also testify regarding the letters received from Chief Chudnow at the Oviedo Police Department. He will explain what was done with the information and the steps that were taken to avoid dispensing prescriptions, as well as his cooperative working relationship with the Oviedo Police Department, which led to the arrest of a number of individuals engaged in doctor shopping and other unlawful activity.

# 24. Melissa Rakauskas, District Pharmacy Supervisor, District 163 (Orlando East)

Melissa Rakauskas will describe her current role as the Pharmacy Supervisor for District 163, which includes Walgreens #06997 in Oviedo, FL. Ms. Rakauskas will then describe the steps that stores in her district took beginning in late 2010 to address the increase of patients with oxycodone prescriptions.

She will further testify that in late 2010, following changes in Florida law, pharmacies in her district began to see an increase in patients with prescriptions for oxycodone. She will testify

that the pharmacists in her district expressed concerns regarding the increased numbers, that they were instructed to use their professional judgment as to whether to fill a prescription, and that her pharmacists refused to fill numerous prescriptions. At this time, she began receiving dozens of calls and emails with complaints about refusals to fill, and her pharmacists began reporting concerns for their own safety from patients whose prescriptions they refused to fill.

She will testify to the remedial measures her district took to reduce the high dispensing numbers at her stores, including geographic, quantity and drug combination limitations, how customers and doctors adapted to evade these controls, and how she held monthly meetings with pharmacy managers to evaluate dispensing protocols.

Ms. Rakauskas will note that the challenges faced by certain pharmacies attempting to make these difficult judgments were compounded by other nearby Florida pharmacies' decisions to discontinue dispensing certain oxycodone medications altogether, which had the effect of concentrating a larger percentage of oxycodone patients at Walgreens #06997.

Ms. Rakauskas will also describe a February 2011 meeting with the Chief of the Oviedo Police Department during which they discussed steps the pharmacists could take to assist with preventing diversion. These anti-diversion efforts were focused on identifying patients that posed a diversion risk. She will further describe subsequent efforts the pharmacists in her district made to work with the Oviedo Police Department and not fill prescriptions for known abusers, such as adding information received from the Police Department to the comments section of patients' profile. Ms. Rakauskas will testify that the steps Walgreens has taken to address oxycodone diversion has reduced the dispensing numbers are her stores to pre-2010 levels.

Finally, Ms. Rakauskas will testify regarding how some prescriptions at her stores are centrally filled at Walgreens' Orlando central fill pharmacy, and how Walgreens' system tracks which prescriptions were filled there.

#### 25. Ed Lanzetti, Market Loss Prevention Director, Market 28

Ed Lanzetti will describe his current role as the Market Loss Prevention Director for Walgreens Market 28, which includes Walgreens #06997 in Oviedo, FL. Mr. Lanzetti will describe the steps that Market 28 Loss Prevention took beginning in late 2010 to address the increase of patients with oxycodone prescriptions.

Mr. Lanzetti will testify that in late 2010, following changes in Florida law, pharmacies in Market 28 began to see an increase in patients with prescriptions for oxycodone. He will testify that the pharmacists in his market expressed concerns regarding the increased numbers, including concerns for their own safety. He will testify to the remedial measures the Loss Prevention team in Market 28 took to reduce the high dispensing numbers, including development of the Focus on Compliance initiative. Mr. Lanzetti will discuss meetings he and the Market Pharmacy Director of Market 28 had with the Pharmacy Managers to discuss the pharmacists' dispensing practices. He will also describe how he tasked the District Loss Prevention Managers and Pharmacy Supervisors in his market with performing additional visits to high-dispensing stores and reviewing dispensing protocols. Mr. Lanzetti will further testify that the initial efforts made to handle the increased dispensing were at the district and market level. He will describe efforts he later made in conjunction with the corporate headquarters to implement standard protocols to ensure consistency across the different markets and districts.

Mr. Lanzetti will describe a February 2011 meeting with the Deputy Chief of the Oviedo Police Department during which they discussed steps the pharmacists could take to assist with preventing diversion. He will further describe subsequent efforts the pharmacists in his market

made to work with the Oviedo Police Department and not fill prescriptions for suspected abusers.

#### VIII. PROPOSED DOCUMENTS

Walgreens incorporates by reference the exhibit list contained in Respondents' Consolidated Witness and Exhibit List, filed concurrently with this Prehearing Statement per this Court's January 10, 2013 Ruling On Respondents' Motion To Consolidate.

#### IX. OTHER MATTERS

- Walgreens anticipates filing multiple motions in limine in advance of trial.
   Walgreens respectfully requests that the Court set a briefing schedule for filing any such motions.
- 2. Walgreens has not yet been provided with the documents that form the basis for DEA's cases. Walgreens anticipates that the Court will set a date for DEA to provide relevant materials and that the parties can work cooperatively to voluntarily produce much of those materials. Until that time, Respondent cannot be certain of the extent to which a subpoena will be required. Respondent therefore asks that the Court set a date following the exchange of documents for filing such motions.

#### X. POSITION REGARDING HEARING LOCATION

Walgreens does not request a change of location for the hearing, so long as DEA agrees to make its witnesses and the DEA witnesses identified by Walgreens in this Prehearing Statement available for trial in Virginia.

### XI. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE

Walgreens anticipates requiring approximately six days to present its case-in-chief in the Pharmacy Matters, exclusive of cross-examination and rebuttal.

Dated: January 18, 2013

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### **CERTIFICATE OF SERVICE**

I certify that on the 18th day of January 2013, I served true and accurate copies of the foregoing by sending the same via United States mail, first-class certified postage prepaid, and via email to the following:

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